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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,341	02/13/2006	Roelof Johannes Kruisinga	13650PCTUS	8991

23719 7590 03/29/2010

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EXAMINER	
JAVANMARD, SAHAR	

ART UNIT	PAPER NUMBER
1627	

MAIL DATE	DELIVERY MODE
03/29/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/529,341	KRUISINGA, ROELOF JOHANNES	
	Examiner	Art Unit	
	SAHAR JAVANMARD	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 November 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-9 and 13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 6-9 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application.
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 20, 2009 has been entered.

Claim(s) 5 and 10-12 are cancelled. Claim(s) 1-4, 6-9, and 13 are pending and are examined herein.

Response to Arguments

In view of Applicant's cancellation of claim 5 the 112 second paragraph rejection is moot.

As set forth on record in the previous office action, the 103(a) rejection of claims 1-9 and 13 as being unpatentable over Glatt (US Patent No. 6,242,446) was withdrawn; however, the rejection statement was inadvertently included in the office action. For the sake of clarity, said rejection is hereby withdrawn.

Applicant's arguments with respect to the 103(a) rejection of claims 2-7 as being unpatentable over Flaugh (US 5,654,325) in view of Wurtman (US 5,449,683) in further

view of Stein (J. Child Adolesc. Psychopharmacol., 1999) and Smucker (American Family Physician, 2001) have been fully considered but are not persuasive.

Applicant points out that because claim 13 was not a part of the rejection that the Examiner concedes that the instant claim is not obvious over the cited art. The Examiner respectfully points out that claim 13 was set forth on the record as being not allowed but was inadvertently not included in the rejection statement. Furthermore, as set forth on the record, the limitation of claim 13 was in fact addressed in Examiner's rejection, therefore it is clear that the instant claim was not a concession to novelty.

Applicant further argues that:

> "Wurtman teaches a dose of melatonin of less than 1.0 mg, as the Examiner concedes in the Office Action at page 4. Therefore, Wurtman specifically teaches away from the 1.0 mg dose of melatonin recited in amended claim 13. Accordingly, Wurtman should not be part of an obviousness rejection of amended claim 13."

In response to this argument, Examiner respectfully notes that, firstly, Applicant's arguments are not commensurate in scope of claims 1-4 and 6-9. Claim 13 is the only claim that sets forth this limitation. Moreover, claim 13 recites that the "medicament is employed in an amount of 1.00 mg/kg in treating ADHD". The claim does not specify the amount of each component, namely, methylphenidate and melatonin that make up this 1.00 mg medicament. Furthermore, Wurtman teaches doses of melatonin in amounts 10 mg or less, in particular less than 1.0 mg of are effective (see office action, page 4). Applicant's contention that Wurtman teaches away from the 1.0 mg dose are not persuasive and the rejection is hereby maintained.

In view of Applicant's amendments, the 103(a) rejection has been modified and is set forth in the Office action below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 6-9 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flaugh (US 5,654,325) of record in view of Wurtman (US 5,449,683) of record in further view of Stein (J. Child Adolesc. Psychopharmacol., 1999) of record and Smucker (American Family Physician, 2001) of record.

Flaugh teaches a method of treating sleep disorders using various melatonin and analogs formula 1 (see summary of the invention, column 2, lines 19-30, for example). The method comprises administering to a mammal, preferably a human, a sufficient amount of one or more compounds of formula I (see column 8, lines 8-11). The compounds can be administered orally in the form of a tablet, pill, powder, and lozenges, and be formulated so as to provide rapid, sustained or delayed release of the active ingredient (see column 8, lines 12-13, 28-29, 45-47, for example).

Flaugh does not teach a method of treating ADHD disorder in a mammal comprising administering melatonin, and a pharmaceutically acceptable salt of

melatonin and a medicament selected from the group consisting of said melatonin analogue in an amount of 0.005 to 1.00 mg/kg.

Wurtman teaches a method of inducing sleepiness and sleep in an individual by administering to that individual a dose of melatonin sufficient to induce sleepiness and sleep (see column 3, lines 57-60). The dose of melatonin administered can be any dose of less than 10 mg of melatonin, which is sufficient to induce sleepiness and sleep in an individual. In particular, a dose of less than 1.0 mg is effective (see column 4, lines 37-43).

Accordingly, one having ordinary skill in the art at the time the invention was made would have found it obvious to formulate a method to treat sleeplessness of Flaugh with the dosage amounts of 0.005 to 1.00, since Wurtman demonstrated a composition with a dose of less than 1.0 mg of melatonin being effective to induce sleep (see column 4, lines 37-43).

The motivation for combining the method of Flaugh with administration of melatonin in amounts of 0.005 to 1.00 is because these low doses of melatonin are effective in inducing sleep in an individual (see column 4, lines 37-43, for example).

Stein teaches a study of sleep problems in stimulant treated and untreated children with Attention Deficit Hyperactivity Disorder (ADHD). Moderate to severe sleep problems occurred at least once a week in 19.3% of children with ADHD. Children with ADHD treated with stimulants were reported to display a higher prevalence of nightly severe sleep problems than did untreated children with ADHD (see abstract, lines 1-9, for example).

Smucker teaches that methylphenidate remains the first choice stimulant for the treatment of ADHD (abstract; page 826, table 5).

Accordingly, one having ordinary skill in the art at the time the invention was made would have found it obvious to formulate a method of treating sleeplessness of Flaugh with a method to treat ADHD, since Stein demonstrated that there is a population overlap of children that have ADHD and sleep problems (see abstract, lines 1-9, for example). Specifically, one would have administered the stimulant methylphenidate based on the teachings of Smucker.

The motivation for combining the method of Flaugh with a method to treat ADHD is because Stein demonstrated that there is a population overlap of children that have ADHD and sleep problems (see abstract, lines 1-9, for example). Thus, treating sleeping disorders as taught by Flaugh would suggest treating ADHD, since sleeping problems as taught by Stein occur in children with ADHD. Therefore, Stein reads on sleeping problems being a species of the genus ADHD, which according to *In re Deuel*, 51 F.3d 1552, 1559, 34 USPQQ2d 1210, 1215 (Fed Cir. 1995) "regardless of how broad, a disclosure of a chemical genus renders obvious any species that happens to fall within it" (see MPEP 2144.08).

Thus, based on the teachings set forth on record, it would have been obvious to one of ordinary skill in the art at the time of the invention to have combined methylphenidate and melatonin for the treatment of ADHD. Furthermore, the order in which the regimen is administered is considered to be a parameter deemed manipulatable to the skilled artisan.

Conclusion

Claims 1-4, 6-9 and 13 are not allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAHAR JAVANMARD whose telephone number is (571) 270-3280. The examiner can normally be reached on 8 AM-5 PM MON-FRI (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/S. J./

Examiner, Art Unit 1617

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1627